

K 070368

1 of 2

Stryker Spine Trio® PS, Trio® Spinal Fixation System  
 & Trio®+ Spinal System

Traditional 510(k) Premarket Notification

510(k) Summary of Safety and Effectiveness  
 Stryker Spine Trio® Plate System

MAY - 4 2007

Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Simona Voic Regulatory Affairs Project Manager Phone: 201-760-8145 FAX: 201-760-8345 Email: simona.voic@stryker.com
Date Prepared	April 17, 2007
Trade Name	Stryker Spine Trio® Plate System
Proposed Class	Class III
Classification Name and Number	Pedicle Screw Spinal System [21 CFR 888.3070(b) (1) & (b) (2)]
Product Code	NKB, MNH, and MNI
Predicate Devices	K043180 – Stryker Spine Trio® Plate System (PS) K060361 – Stryker Spine Xia® and Xia® 4.5 Spinal Systems K060369 – Stryker Spine Opus™ Spinal System
Device Description	The Stryker Spine Trio® Plate System is comprised of spinal screws, plates and locking components, fabricated from Titanium alloy.

Stryker Spine Trio® PS, Trio® Spinal Fixation System

&amp; Trio®+ Spinal System

	<p>This submission adds the Class III indications per product code NKB, 21 CFR 888.3070(b)(2), but no additional components. The expanded indications for use statement for the TRIO® PS has also been modeled on the suggested indications for use statement for posterior thoracolumbar systems (product codes MNI, MNH, NKB) suggested by FDA in FDA's "Guidance for Industry and FDA Staff: Spinal System 510(k)s," dated May 3, 2004.</p>
Intended Use	<p>The Stryker Spine Trio® Plate System is intended for posterior, noncervical (T10-S1) pedical and nonpedical fixation of the spine for the following indications:</p> <ul style="list-style-type: none"> <li>• Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);</li> <li>• Spondylolisthesis;</li> <li>• Trauma (i.e., fracture or dislocation);</li> <li>• Spinal stenosis;</li> <li>• Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);</li> <li>• Tumor;</li> <li>• Pseudoarthrosis; and</li> <li>• Failed previous fusion.</li> </ul>
Summary of the Technological Characteristics	<p>Testing in compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 was performed for the Stryker Spine Trio® Plate System and was presented in their respective predicate 510(k)s. This 510(k) contains no new components. It only addresses the additional Class III indications associated with product code NKB.</p>

Stryker Spine Trio® PS, Trio® Spinal Fixation System  
& Trio®+ Spinal System

Traditional 510(k) Premarket Notification

510(k) Summary of Safety and Effectiveness  
Stryker Spine Trio® Spinal Fixation System

Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Simona Voic Regulatory Affairs Project Manager Phone: 201-760-8145 FAX: 201-760-8345 Email: <a href="mailto:simona.voic@stryker.com">simona.voic@stryker.com</a>
Date Prepared	April 17, 2007
Trade Name	Trio® Spinal Fixation System
Proposed Class	Class III
Classification Name and Number	Pedicle Screw Spinal System 21 CFR 888.3070(b) (1) & (b) (2)
Product Code	NKB, MNH, and MNI
Predicate Devices	K032855 – Stryker Spine MAPS System K052971 - Stryker Spine Trio® Spinal Fixation System K060361 – Stryker Spine Xia® and Xia® 4.5 Spinal Systems
Device Description	The Stryker Spine Trio® Spinal Fixation System is comprised of spinal screws, rods, and offset connectors, fabricated from Titanium alloy.

Stryker Spine Trio® PS, Trio® Spinal Fixation System  
 & Trio®+ Spinal System

Traditional 510(k) Premarket Notification

	<p>This submission adds the Class III indications per product code NKB, 21 CFR 888.3070(b)(2), but no additional components. The expanded indications for use statement for the TRIO® Spinal Fixation System has also been modeled on the suggested indications for use statement for posterior thoracolumbar systems (product codes MNI, MNH, NKB) suggested by FDA in FDA's "Guidance for Industry and FDA Staff: Spinal System 510(k)s," dated May 3, 2004.</p>
Intended Use	<p>The Stryker Spine Trio® Spinal Fixation System is intended for posterior, noncervical pedicle and non-pedicle fixation of the spine. The Stryker Spine Trio® Spinal Fixation System is indicated for:</p> <ul style="list-style-type: none"> <li>• Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);</li> <li>• Spondylolisthesis;</li> <li>• Trauma (i.e., fracture or dislocation);</li> <li>• Spinal stenosis;</li> <li>• Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);</li> <li>• Tumor;</li> <li>• Pseudoarthrosis; and</li> <li>• Failed previous fusion.</li> </ul> <p>The Trio® Spinal Fixation System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods, and the Multi-Axis Cross Connectors.</p>
Summary of the Technological Characteristics	<p>Testing in compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 was performed for the Stryker Spine Trio® Spinal Fixation System and presented in K032855 and K052971. This 510(k) contains no new components. It only addresses the additional Class III indications associated with product code NKB.</p>

K070368

P6-3

Stryker Spine Trio® PS, Trio® Spinal Fixation System  
 & Trio®+ Spinal System

Traditional 510(k) Premarket Notification

510(k) Summary of Safety and Effectiveness  
 Stryker Spine Trio®+ Spinal System

Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Simona Voic Regulatory Affairs Project Manager Phone: 201-760-8145 FAX: 201-760-8345 Email: <a href="mailto:simona.voic@stryker.com">simona.voic@stryker.com</a>
Date Prepared	April 17, 2007
Trade Name	Stryker Spine Trio®+ Spinal System
Proposed Class	Class III
Classification Name and Number	Pedicle Screw Spinal System 21 CFR 888.3070(b) (1) & (b) (2)
Product Code	NKB, MNH, and MNI
Predicate Devices	K052971 - Stryker Spine Trio® Spinal Fixation System K062698 – Stryker Spine Trio®+ Spinal System K060361 – Stryker Spine Xia® and Xia® 4.5 Spinal Systems
Device Description	The Stryker Spine Trio®+ Spinal System contains spinal screws, rods, and connectors, fabricated from Titanium alloy. This submission adds the Class III indications per product code NKB,

Stryker Spine Trio® PS, Trio® Spinal Fixation System  
 & Trio®+ Spinal System

## Traditional 510(k) Premarket Notification

	<p>21 CFR 888.3070(b)(2), but no additional components.</p> <p>The expanded indications for use statement for the TRIO® + Spinal System has also been modeled on the suggested indications for use statement for posterior thoracolumbar systems (product codes MNI, MNH, NKB) suggested by FDA in FDA's "Guidance for Industry and FDA Staff: Spinal System 510(k)s," dated May 3, 2004.</p>
Intended Use	<p>The Stryker Spine Trio®+ Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation of the spine.</p> <p>The Stryker Spine Trio®+ Spinal System is indicated for:</p> <ul style="list-style-type: none"> <li>• Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);</li> <li>• Spondylolisthesis;</li> <li>• Trauma (i.e., fracture or dislocation);</li> <li>• Spinal stenosis;</li> <li>• Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);</li> <li>• Tumor;</li> <li>• Pseudoarthrosis; and</li> <li>• Failed previous fusion.</li> </ul> <p>The Trio®+ Spinal System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods, Xia® Pre-bent Rods, and the Multi-Axis Cross Connectors.</p>

KO70368  
3 of 3

Stryker Spine Trio® PS, Trio® Spinal Fixation System  
& Trio®+ Spinal System

Traditional 510(k) Premarket Notification

Summary of the Technological Characteristics	Testing in compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 was performed for the Stryker Spine Trio®+ Spinal System, and was presented in the respective predicate 510(k)s. This 510(k) contains no new components. It only addresses the additional Class III indications associated with product code NKB.
--	--



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Stryker Spine Corporation  
c/o Ms. Simona Voic  
2 Pearl Court  
Allendale, New Jersey 07401

MAY - 4 2007

Re: K070368

Trade Name: TRIO® Plate System, TRIO® Spinal Fixation System, TRIO®+ Spinal Fixation System

Regulation Number: 21 CFR 888.3070

Regulation Name: Pedicle Screw Spinal System

Regulatory Class: III

Product Code: NKB, MNH,MNI

Dated: April 13, 2007

Received: April 17, 2007

Dear Ms. Voic:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the device are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

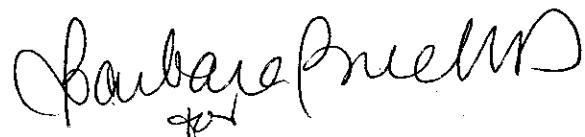
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Christopher Klaczyk

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K070368

Device Name: Stryker Spine Trio® Plate System

### Indications For Use:

The Stryker Spine Trio® Plate System is intended for posterior, noncervical (T10-S1) pedical and nonpedical fixation of the spine for the following indications:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

Prescription Use X

AND/OR

Over-The-Counter Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Barbara French, M.D.

(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

Page 1 of 1

510(k) Number K070368

## Indications for Use

510(k) Number (if known): K070368

Device Name: Stryker Spine Trio® Spinal Fixation System

### Indications For Use:

The Stryker Spine Trio® Spinal Fixation System is intended for posterior, noncervical pedicle and non-pedicle fixation of the spine.

The Stryker Spine Trio® Spinal Fixation System is indicated for:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Trio® Spinal Fixation System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods, and the Multi-Axis Cross Connectors.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Charles Boren  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

Page 1 of 1

510(k) Number K070368

## Indications for Use

510(k) Number (if known): K070368

Device Name: Stryker Spine Trio®+ Spinal System

### Indications For Use:

The Stryker Spine Trio®+ Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation of the spine.

The Stryker SpineTrio®+ Spinal System is indicated for:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Trio®+ Spinal System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods, Xia® Pre-bent Rods, and the Multi-Axis Cross Connectors.

Prescription Use X

AND/OR

Over-The-Counter Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carla Lee  
Division Sign-Off

**Division of General, Restorative,  
and Neurological Devices**

Page 1 of 1

510(k) Number K070368